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A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation

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Products arising from modern biotechnology provide new opportunities to achieve sustainable productivity gains in agriculture. Concerns over their possible environmental and health implications stimulated regulatory mechanisms for food safety and environmental risk assessment. Over the past two decades, national biosafety frameworks, guidelines, and regulatory systems have often been implemented on a "piece-by-piece" basis in response to the demands or urgent needs of the moment. Ideally, a biosafety system would be developed from a comprehensive plan. However, building such a system and making it operational is complicated by the fact that there is no single best approach nor standard that reflects national environmental, cultural, political, financial, and scientific heterogeneity.

Given these challenges and difficulties inherent in building regulatory systems and needed capacity, the International Service for National Agricultural Research (ISNAR) convened an expert consultation in July 2001. The purpose of this meeting was to develop a conceptual framework to address regulatory implementation and capacity-building needs of developing countries and Parties to the Protocol. A framework for implementing national biosafety systems emerged, which consists of the following five elements:

- *national policies, strategies, and research agendas regarding biosafety;*
- *national inventory and evaluation;*
- *the knowledge, skills, and capacity base to develop and implement a biosafety system;*
- *development of regulations; and*
- *implementation of regulations.*

The conceptual framework clarifies critical decision points in the development of a national biosafety system, systematically examines choices among policy options, and delineates some of the scientific and social dimensions of these options. It complements ongoing regional and global projects that facilitate the development of national biosafety guidelines and frameworks.

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Introduction

The conceptual framework for biosafety implementation presented in this paper is based on a synthesis of the contributions made to an international expert consultation entitled “A Framework for Biosafety Implementation: A Tool for Capacity Building.” Background for the framework and substantial documentation can be found in the full proceedings (ISNAR, forthcoming)[1].

The framework expands on the conceptual basis used for ISNAR’s national biosafety system studies in Egypt and Argentina (Madkour, El-Nawawy, and Traynor 2000; Burachik and Traynor 2001) and on concepts and lessons derived from other national, regional, and international experiences analyzed during the consultation.

The purpose of this framework is to address national needs regarding regulatory implementation and capacity building, in particular of those countries that are Parties to the Cartagena Protocol on Biosafety. The framework is meant to complement the UNEP/GEF Global Project on the Development of National Biosafety Frameworks (Briggs 2001) by providing guidance on the design and implementation of regulatory frameworks and related capacity-building initiatives. It is not intended to be a common road map for all Parties or countries to follow. Instead, the objective is to clarify critical decision points in the development of a national biosafety framework, to examine choices among policy options, and to delineate some of the scientific and social dimensions of these options. The consequences of policy choice on the efficiency and effectiveness of biosafety regulations are presented in more detail by McLean et al. (2001).

The Cartagena Protocol on Biosafety

Adopted in January 2000 as a supplement to the Convention on Biological Diversity, the Cartagena Protocol on Biosafety (the Protocol) addresses the safe transfer, handling, and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity, taking into account risks to human health and focusing specifically on transboundary movements (CBD Secretariat, 2000). The Protocol allows governments to indicate their willingness to accept imports of agricultural commodities that include LMOs by communicating their decision to the world community via the Biosafety Clearing House, a mechanism set up to facilitate the exchange of information on, and experience with, LMOs. The aim is to ensure that recipient countries have both the opportunity and the capacity to assess risks involving the products of modern biotechnology.

National, regional, and international agencies have recognized that successful implementation of the Protocol is contingent on the development of national biosafety capacity in countries that have yet to establish, or are in the process of establishing, biosafety systems. The Protocol makes clear that Parties to the Protocol must develop or have access to “the necessary capacities to act on and respond to their rights and obligations.” The Protocol provides considerable flexibility as to how importing countries may meet their obligations with respect to risk-management decision making and to the implementation of these decisions. As stated in Article 16, which deals with Risk Management, each Party has an obligation to “establish and maintain appropriate mechanisms, measures, and strategies to regulate, manage, and control risks identified in the risk assessment provisions” (CBD Secretariat 2000).

The Five Elements of the Conceptual Framework

The framework addresses five elements, identified by the consultation participants as fundamental to the development and implementation of a national biosafety system (Figure 1). The first two—national policies, strategies, and research agendas regarding biotechnology and biosafety, and a national inventory and evaluation—provide the foundation for subsequent regulatory implementation. The next element—requisite knowledge, skills, and capacity base—is the resource environment within which the final two elements occur: development of regulations and implementation of regulations.

As described here, national policies and the inventory and evaluation do not lend themselves to the format used to analyze the other three elements, where decision points, policy options, and key questions were identified. National biosafety strategy is discussed conceptually, and national appraisal is addressed by broadly identifying the capacities available and needed to implement the Protocol. Three crosscutting issues, common to each element of the framework, are also identified and discussed: transparency, public participation, and resources.

Using this framework to help build more comprehensive regulatory systems gains importance as developing countries contend with increasing numbers of applications for confined field trials and commercial

1. The full proceedings and subsequent research provide comprehensive treatment of the framework by examining the specific elements and decision-making processes, which is not possible in this briefing paper.

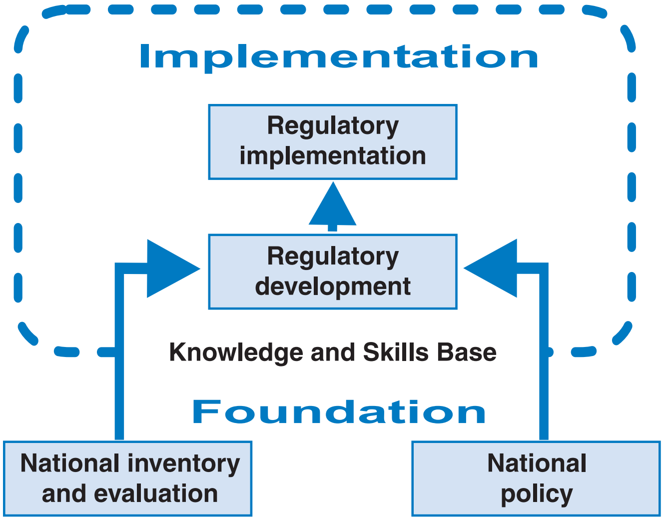

Figure 1. Basic elements providing for implementation of biosafety regulations

release. Expanding needs for assessments require careful planning to build the necessary capacity base and to clarify policy and system objectives to expedite review decisions. Otherwise, review procedures will be delayed not by the assessment, but by lack of clarity regarding policy or political matters (Paarlberg 2001).

Element 1: National Policies and Strategies

Ideally, the evolution of a national biosafety system begins with the elaboration of a national policy consistent with other policy objectives related to food, agriculture, the environment, and sustainable development. This would form the basis for the development of specific legislation and/or regulations, leading finally to the design and implementation of the structural elements necessary for risk analysis, inspection, monitoring, and enforcement. A national assessment of the existing scientific and technical capacity would support and inform the design process. This ideal progression is rarely the case. In reality, portions of these activities are often completed simultaneously, usually in an attempt to meet short-term needs.

The importance of a national biosafety strategy cannot be overstated as it provides a set of principles to guide subsequent development and implementation of a biosafety system and regulations. Biosafety policy articulates a national approach to biosafety regulation and the goals and objectives of the regulatory framework. It serves to integrate political, social, ethical, health, economic, and environmental considerations into decisions regarding the safe and appropriate use of biotechnology methods and products. A national strategy may provide direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations.

Whether formulated prior to the existence of a regulatory system, or subsequently, a national biosafety policy should serve to articulate a framework whereby seemingly disparate goals, such as economic and regional development, and environmental protection, may be integrated and communicated as a single national vision. In addition, a national strategy should provide for the creation of some form of an advisory committee to serve as a focal point for initiating public dialogue and addressing crosscutting issues related to the ethical, legal, and social implications of biotechnology.

Element 2: National Inventory and Evaluation

A nation's political and legal environment, including its societal philosophy, form of government (e.g. monarchy, republic, tribal), legal framework (e.g. constitution, courts), and domestic stability, should contribute to framing the scope and content of a national biosafety system. An inventory and evaluation of national priorities, agricultural policies, existing regulatory regimes, and national scientific and technical means is ideally a prerequisite to the development and implementation of biosafety-related policies and regulations. This national appraisal provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened. The inventory should catalog the following elements:

- existing regulatory structures and legislation pertaining to the import and export of agriculture commodities, environmental protection, animal and human health safety, and biotechnology;
- existing mechanisms for the development of public policy, legislation, and regulations;
- existing human, financial, and scientific infrastructure;
- the current status of biotechnology research and development, including programs for the safe use and handling of LMOs;
- existing mechanisms for regional cooperation and regulatory harmonization;
- existing capacity building programs;
- the role of civil society in processes for policy and regulatory development; and
- administrative and enforcement capacity.

As previously mentioned, a country rarely reviews all of these items prior to actually managing/regulating LMOs. More commonly, and perhaps more practically, countries evaluate their national capacities on a stepwise basis, as dictated by domestic needs: the capability to manage LMOs in contained facilities, followed by confined small- and large-scale field trials, and finally, the unconfined release of an LMO. In countries that do not have domestic biotechnology programs, the national inventory and evaluation may be framed exclusively by the requirements of the Protocol and the consideration whether the country is importing commodities with LMOs for processing or for cultivation.

Element 3: Scientific Knowledge, Skills and Capacity Base

The human resource environment that both enables and limits biosafety implementation is shaped by the scope and quality of competency in the disciplines of biological science; expertise in information acquisition, communications, and management; and experience in critical thinking, analysis, and decision making. Regardless of whether a biosafety (or even biotechnology) policy is in place, or a national inventory and evaluation has been conducted, these capacities have an overriding influence on the development and implementation of a biosafety system. A thin, weak, or limited knowledge and skills base tends to produce regulations that are highly protective, at the expense of innovation, poorly defined or inconsistent, comparatively rigid, and/or narrowly interpreted. A deep and broad knowledge, skills, and capacity base will foster more latitude in regulatory development and more flexibility in regulatory implementation.

Fundamental to any national biosafety system is a strong base of scientific knowledge in support of the regulatory system and the development of core competencies in biotechnology product evaluation (figure 1; table 1). These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring.

Decision point 1: Coordinating scientific expertise

As the science involved in the creation of LMOs advances, and the products themselves become more complex, there is an increasing need to strengthen the science base supporting risk assessment and regulation. Skills must be developed for biotechnology product evaluation and to maintain parity between risk assessors and their counterparts working to create products. This requires constant updating on new scientific advances, without which a regulator's knowledge base has a limited life expectancy.

Adequate scientific capacity provides improved assessment of potential risks and/or benefits, and can improve the quality of risk-management decisions and the capability for inspection and monitoring. The limitations in national scientific and technical capacity identified during the inventory and evaluation can be addressed through a coordinated approach, which would aim to enhance domestic expertise through training while relying on subregional, regional, and/or international cooperation in performing risk assessments, on outside experts, and on the international academic community.

Decision point 2: Locating the science evaluation function

Structurally, different approaches to securing scientific advice for decision making can be taken. In considering

Table 1. Key Decision Points and Policy Options Related to Science and the Knowledge Base Supporting Biosafety Regulation

Decision Point	Policy Options	Key Questions
1. Coordinated approaches to incorporating scientific advice into biosafety decision making	Development of national capacity for scientific risk assessment *vs.* coordinating risk assessment at a regional or subregional level Reliance on international experts *vs.* domestic self-sufficiency and capability	What is the state of biotechnology development nationally: is this expected to grow, and is there an existing base of expertise which can be employed or enhanced? Does all of the necessary expertise reside within the region, or must this be supplemented by the inclusion of external reviews and/or training? Are there shared values and regulatory approaches among potential collaborating countries within the region? Is there a previous history of collaboration or coordination in other regulatory arenas?
2. Locating the science evaluation function within the regulatory system	Development of core competencies for risk assessment within government departments and agencies *vs.* reliance on expert advisory committees *vs.* a combination of both in-house and external scientific expertise. Concentrating the risk-assessment function within a single identifiable body *vs.* distributing this function among different government departments and ministries	Does the appropriate expertise currently reside within the regulatory authority, or is it primarily within academic and other institutions? Is there government support and commitment for the development of expertise within regulatory agencies? Within government departments, are there adequate foresight mechanisms in place to identify potential knowledge gaps, and are there existing avenues to access training or the recruitment of "new" knowledge? Should expert committees and advisory panels be used in all cases of product approval, or only to address specific issues of scientific uncertainty?

the risk assessment of biotechnology products, some countries have implemented a system of expert advisory committees, while others have relied primarily on scientists and professionals working within government agencies. In the latter approach, the mandate for risk assessment may be vested within a single agency exclusively tasked with regulating products of biotechnology (e.g., a gene technology regulator) or it may be distributed between agencies in accordance with their existing responsibilities (e.g., departments of health, agriculture and/or environment).

In general, independent advisory committees have more transparent accountability frameworks than government departments and agencies, where the range of expertise and academic credentials of risk assessors is rarely published. However, advisory bodies may suffer from the fact that committee members are part-time volunteers who cannot devote their full energies to risk assessments. An approach to LMO regulation whereby product evaluations performed by competent scientists within a regulatory agency are supplemented by the results of issue-specific expert panel consultations may combine the best of both approaches described above.

Element 4: Development of Regulations

Consistent with the vision of a national strategy, biosafety regulations may be developed to effect specific public-policy goals. Decisions on an appropriate regulatory structure and the legal and political means by which such a structure can be implemented should be informed by the national inventory and evaluation, and through extensive consultation with stakeholders, including the public.

Some key elements to be considered in developing a regulatory framework are (1) the legislative framework,; (2) regulatory "triggers," i.e., the criteria that— individually or combined—make a product subject to regulatory review, (3) transparency and public involvement in the policy making, and regulatory decision making processes, and (4) approaches to risk assessment and risk management. These considerations introduce decision points where the choices made will have a significant effect on the subsequent development, implementation, and operation of the biosafety system. Critical decision points together with policy options and key questions are elaborated in table 2 and discussed below.

Decision point 1: Legislative framework

The foundation of any biosafety regulatory system is authority. Authority refers to the enabling legislation (acts, laws, decrees, and government orders) governing biosafety. At the national level, this is the authority to promulgate regulations, supersede subnational authorities, intercede in trade or domestic movement, and implement enforcement agencies. The establishment of regulations (or executive orders) is necessary for enacting prohibitions, restrictions, and requirements under the authority of national legislation. Authority is also used to create policy instruments such as permits, guidelines, information requirements, etc.

In countries with established biosafety programs, regulatory oversight of LMOs generally began with nonbinding, voluntary guidelines. The designated authorities developed information guidelines and technology developers abided by these, and there is no evidence that the nonstatutory management of LMOs under voluntary regimes has compromised environmental safety. The benefits of voluntary guidelines include the speed by which they can be put in place and the flexibility they allow to adopt revisions incorporating new information requirements without delay. However, in the absence of a legal instrument, the public may not have confidence that the government is adequately regulating these products, or that developers are complying with voluntary guidelines. Additionally, enforcement powers may be limited in a voluntary system, depending on both the discretionary power of the competent authority to penalize a proponent for noncompliance, and on opportunities for redress through the courts, should negligence be suspected.

Countries electing to develop a mandatory biosafety system have two choices for establishing legally binding regulations: (1) they can develop a new act and regulations to specifically address LMOs, or (2) they can regulate LMOs under the auspices of existing legal instruments such as acts, regulations, and ministerial or presidential decrees.

The advantages of the former are the following:

- An act can be developed to specifically address the product or process to be regulated.
- It can provide flexibility so that new technical advances can also be captured without significant regulatory amendment.
- It can be perceived by the public as a positive response to addressing concerns about the safety of LMOs.

The following are disadvantages of developing a new act:

- Passing an act into law make take long, in particular in the politically charged environment around LMOs existing in so many countries today.
- It may result in the regulation of LMOs in perpetuity so that, even if a history of safe use of a specific genetic element is established, LMOs with this element will still be singled out for exceptional regulatory oversight.

Decision point 2: Regulatory triggers

The Biosafety Protocol is limited to addressing biosafety concerns that may be associated with the products of modern biotechnology, irrespective of the trait or traits that an LMO may express. This is an approach that relies on the use of *in vitro* nucleic acid or cell-fusion techniques for producing LMOs as the trigger for determining what to regulate. Process-based triggers are the rule in almost all countries that have developed national biosafety regulatory systems; there are exceptions, however, where the novelty of the trait determines the extent of regulatory oversight and not the process by which the trait was introduced. While such a product-based approach to defining the object of regulation is truest to the scientific principle that biotechnology is not inherently more risky than other technologies that have a long and accepted history of application in agriculture and food production, it is less prescriptive than process-based regulatory systems.

It is more challenging for both developers and regulators to determine when a plant is in fact a "plant with a novel trait" as opposed to the simple test of whether an LMO was produced using recombinant DNA or cell-fusion technologies. Additionally, ensuring compliance with regulations prohibiting the importation of unapproved plants with novel traits is technically and financially impracticable. Unlike those products of genetic engineering where the genetic basis of the novel trait (e.g., the introduced DNA) is well characterized, plants with novel traits produced by accelerated mutagenesis or wide outcrossing, for example, may not have any readily identifiable markers suitable for diagnostic screening.

Decision point 3: Approaches to risk assessment and risk management

Scientific risk assessment is the cornerstone of biosafety regulatory systems and public-policy decisions related to the safety and acceptability of LMOs. A strong scientific capacity and knowledge base is viewed as key

Table 2. Key Decision Points and Policy Options Related to Biosafety Regulation Development

Decision Point	Policy Options	Key Questions
1. Legislative framework	Existing, amended, or new legislation Centralized (e.g., single "gene technology regulator") *vs.* Distributed responsibility/authority	Is the scope of existing legislation sufficient to encompass products of biotechnology? Are there existing mechanisms for coordination of risk-assessment and risk management functions in the various government agencies that may be involved in biosafety regulation?
2. Regulatory triggers	Scope of regulatory oversight—product *vs.* process Establishment of appropriate instruments for comparing assessments – impacts on unmanaged *vs.* managed ecosystems; Comparisons involving conventional, subsistence, or organic agriculture;	Should the trigger for regulatory oversight be based on some product characteristic or a process used in its manufacture? What types of products and/or processes should be included? (e.g., imports, exports, animals, commodities, seed, processed products, etc.) To what extent should scientific research, including the manipulation of genetically modified organisms, be regulated and/or controlled?
3. Approaches to risk assessment and risk management	Evidence-based scientific evaluation *vs.* consideration of socioeconomic factors Consideration of risks and benefits *vs.* only risks Definition of safety standard(s)	How are risk factors for a particular commodity determined? How should international standards and agreements (e.g., concepts of familiarity, substantial equivalence, and reasonable certainty) be incorporated? Should the assessment process distinguish demonstrable *vs.* hypothetical risks? Who should be responsible for undertaking the necessary experimentation, testing and/or surveillance to satisfy risk assessment data requirements? Other than risks, should the assessment include an examination of potential benefits or other issues? Should broader social, ethical, or economic issues be factored into risk-assessment decisions?
4. Transparency and public involvement	Public consultation (e.g., soliciting and acting on public input) *vs.* public notification, either before and/or after the regulatory decision Public involvement in the development of legislation and/or regulation *vs.* involvement in the decision-making process	Should citizens be engaged in, or informed of, changing regulations and/or policy related to biotechnology, or the products derived there from? In advance of a regulatory decision, should the public be notified of biotechnology products undergoing evaluation? With respect to the application, should environmental or human health supporting data be publicly disclosed? In advance of a regulatory decision, should public input be solicited and considered?

to identifying hazards and assessing their impacts and likelihood.

There is good international consensus that risk assessments should focus on scientific consideration of the evidence or potential for adverse impact. This consensus is reflected in Article 15 of the Protocol, which asserts: "Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner [...]." Annex III to the Protocol provides further details on risk assessment principles and a suggested methodology. There may be cases where other, nonscience factors are essential for making final decisions, however, these considerations should be separate from the risk assessment process as such.

Policy decisions regarding the deliberate environmental release of LMOs represent one area where scientific advice has played a crucial but varying role in different countries. In Canada and the USA, science largely "determines" the regulatory decision, while in the European Union, science is one consideration among other factors that play a crucial role in the decision making process.

Decision point 3 (continued): Approaches to risk assessment and risk management—socioeconomic considerations

Worldwide, the most common approach to risk assessment is based on a consideration of the scientific evidence regarding various risk factors, tempered with varying degrees of "precaution." Seldom are benefits or economic issues considered, and nowhere is there a systematic consideration of social or ethical concerns related to the approval of a specific product.

The application of modern biotechnology to the genetic modification of plants and in food production generally has given rise to widespread discussion on its social, ethical, and at times economic acceptability. How should these concerns, which largely relate to justice, beneficence, and respect for cultural diversity, be considered within a product approval system, or more generally, within a national biosafety strategy?

There is no consensus on how best to reflect socioeconomic concerns within a regulatory system. The consideration of quantifiable economic impacts may be considered a justifiable component of the product approval process. In such cases, the creation of a regulatory structure that allows separation of the scientific risk assessment and regulatory decision-making processes is advisable. Such a tiered approach provides a system in which the regulatory decision is "informed," both by the scientific risk assessment and by other considerations. The drawback of this approach concerns the extent to which decisions may be subject to "political interference" or impinge on existing international trade agreements. Adequate transparency, openness, and objectivity are key to the successful implementation of such an approach.

It does not appear feasible, nor advisable, to include broader ethical and social considerations (excluding economic consequences) into the process for individual product approvals. These important considerations are best dealt with by establishing ethics committees or other expert bodies responsible for providing governments with policy advice on ethical, legal, or social issues related to the adoption of new technologies. The exploration of ethical issues can serve both to develop a public consensus on the acceptability of various technologies and to guide the evolution of a policy framework for regulation.

Decision point 3 (continued): Approaches to risk assessment and risk management—international agreements and trade

Beyond the Cartagena Protocol, there are other international agreements, conventions and treaties, such as trade agreements governed by the World Trade Organization (WTO)[2], and the Codex Alimentarius on food standards, governed by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations. Implementation of these agreements may impact directly or indirectly on the development of a biosafety regulatory system. It is important that obligations under these agreements be considered when developing biosafety regulations, particularly for those countries that anticipate exporting LMOs. Where possible, attempts should be made to harmonize with risk assessment criteria and standards that have achieved international acceptance in either practice or principle.

Decision point 4: Transparency and public involvement

For this discussion, please refer to "Crosscutting Issues" on page 10.

Element 5: Implementation of Regulations

In general, the central issues around the implementation of biosafety regulations involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication, while managing within existing financial, technical, and human resource constraints (Cohen 2001). Decisions made during the implementation phase impact directly on the economic costs associated with assessing and mitigating risks and ensuring compliance. In addition to the key decision points and policy options outlined in table 3, other

2. Relevant examples include the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

Table 3. Key Decision Points and Policy Options Related to Biosafety Regulation Implementation

Decision Point	Policy Options	Key Questions
1. Harmonize risk assessment at subregional or regional level	Harmonize legislative authority *vs*. establish a shared "checklist" of essential elements of biosafety assessment for incorporation into existing national legal systems Establish agreement on general principles for biosafety risk assessment *vs*. establish agreement on methodologies and information requirements for risk analyses Harmonize administration of biosafety systems to facilitate information exchange, notification, and compliance/monitoring activities	Is there a history of subregional or regional regulatory harmonization? Are there shared goals and objectives for cooperation? Are there established mechanisms or processes to facilitate regional cooperation?
2. International harmonization of risk assessments (for applications relating to products previously approved in another regulatory jurisdiction)	Accept as equivalent to a domestic evaluation *vs*. require complete assessments domestically	What conditions would have to be met to establish equivalence for international data? Should there be a distinction between the equivalency of environmental and human food safety risk assessments?
3. Scientific evaluation and the breadth and depth of information required to reach a decision	Basic information (e.g., scientific rational based on previously published studies), intermediate, or extensive	Has the same product been approved in another regulatory jurisdiction, or has a similar product been approved domestically? Are there closely related wild species in the recipient country, or other complicating factors? Who is responsible for undertaking the necessary experimentation, testing and/or surveillance to satisfy risk assessment data requirements? Whether this activity occurs within the regulatory system (i.e., within government), or externally, how are the veracity of the data and the scientific soundness of the approach verified?
4. Transparency of the risk assessment process and risk assessment decisions	Internal *vs*. external reviews and/or supplementary opinions Publication of deliberations/conclusions/ /decisions, before or after the fact	What formal, or informal, mechanisms exist for incorporating outside scientific expertise into the risk assessment process? How are petitioners informed of the regulatory requirements, including assessment guidelines, for biotechnology products? With respect to the application and supporting data, how much information is disclosed and how is the issue of confidential business information dealt with? How are regulatory decisions communicated to the public? How is new scientific information that may impact a prior regulatory decision used to reevaluate decisions and communicated to the public?
5. Public engagement in the risk-management decision	No public involvement in the regulatory decision making process, or only in certain cases *vs*. requesting public input in all cases	What are the mechanisms for soliciting and recording public input? Is there a distinction between stakeholder groups (e.g., scientific societies, industry groups, nongovernmental organizations) and the public? If it does occur, how are public comments and/or concerns addressed and reflected in the regulatory decision? To what extent are the comments and their responses are made public?
6. Post-commercialization monitoring and surveillance	No post-market monitoring vs. short-term follow-up (less than 5 years) vs. long-term follow-up (more than 5 years) Follow-up for all organisms, or only for certain organisms (e.g., those with wild relatives in the host country Time-limited *vs*. open-ended approvals	If post-market product surveillance does occur, are there requirements for the segregation of agricultural commodities and/or labeling of food products? How are the results of post-commercialization monitoring communicated with the public? What are the regulatory requirements, if any, for post-approval review and/or consideration of new information?
7. Compliance and enforcement	Levels of inspection and audit Imposition of administrative and monetary penalties Trade sanctions	

important considerations include opportunities for international cooperation at a technical level (e.g., sharing human and scientific resources and expertise) and establishing a scheduled phasing-in of regulations (e.g., initial voluntary guidelines entrenched in legislation over time). The final step—putting the system into operation—entails meeting requirements for the four elements that allow biosafety implementation (Traynor 1999) as follows:

- The regulations or guidelines clearly define the structure of the biosafety system.
- The people are knowledgeable and well trained.
- The review process is based on up-to-date scientific information.
- Feedback mechanisms are used to incorporate new information and revise the system as needed.

Decision point 1, 2, and 3: Regional and international harmonization

Implicit in the Cartagena Protocol is the assumption that subregional cooperation in information sharing and harmonizing legal and regulatory systems is crucial for effective management of transfer of LMOs across borders. Successful harmonization depends on the following key factors: (1) the adoption of common values and objectives, (2) shared interest and concerns; the existence of economic and other benefits, (3) the need to overcome differences and avoid disputes, (4) the need to cooperate against other interests, and (5) the need to simplify procedures. In the absence of some or all of these factors, the chances of achieving effective harmonization are limited. Harmonization can occur on three fronts - authority, risk analysis, and administration - as discussed below.

Harmonization of **authority** is the most difficult to achieve and the delegation of national authority to a regional or subregional body rarely occurs, if at all. Because of the diversity of legal systems, the development of model legislation or regulations is problematic. A more reasonable goal is to develop a checklist of essential elements that can be incorporated into national legal systems in different ways. Harmonization should focus on identifying and securing agreement on these core elements, while balancing international and regional obligations and objectives.

The harmonization of **risk analysis** principles, information requirements, and standards of assessment can be instrumental to maximizing the use of institutional, financial, technical, and human resources within a region. For small countries, where the national science community is small, the ability to capitalize on external expertise and information may be a crucial condition for implementing the Protocol. Harmonization of analysis can occur at two levels. The first is conceptual, i.e., agreement on general principles of risk assessment. Examples of this include the Protocol itself, as well as consensus documents on food safety and environmental risk assessment. Such documents form the basis for international agreements on risk assessment. The second level is technical and involves agreement on methodologies, information requirements, or criteria for determining unacceptable risks.

Harmonization of **administrative functions** concerns procedures for the implementation of norms, rules, and standards. It includes things like record keeping, communication, information exchange, and notification systems. Within the context of the Protocol, one example of this type of harmonization will be provided in the form of a Biosafety Clearing House, which is the mechanism for sharing scientific, technical, environmental, and legal information relating to the risk assessment and transboundary movement of LMOs among the Parties.

Decision point 4 and 5: Transparency of decisions and public engagement

Ideally, the process used to develop a national biosafety system should be transparent and the level of involvement of the public and/or stakeholder or special interest groups as legislation, regulations, or guidelines are being developed, ought to be considered. Practically, the extent to which this happens mostly depends on past practices of the government in other areas. Additionally, decisions must be made as to the degree of transparency and public involvement that the system will afford after it is implemented, e.g., should the public be consulted or notified before or after a regulatory decision or policy change is made. It is advisable for governments to proactively support a development process that is open and permits some form of public engagement prior to the promulgation of acts and regulations or to the publishing of guidelines.

As a minimum, the process and criteria for risk assessment and risk management should be widely published so that developers, stakeholders, and the public can trust the biosafety system to be both credible and predictable. Some jurisdictions have surpassed this level: they additionally notify the public when applications for the environmental safety assessment of a genetically modified organism are received by the competent authorities, and also when a regulatory decision is made.

Within the context of implementing a biosafety system, opportunities for public engagement may be provided through formalized requests for public input. Most commonly, the public is provided with an opportunity to evaluate summary information about the LMO under review and to submit comments in this regard.

Decision points 6 and 7: Monitoring and compliance

Internationally, no country has implemented a systematic process of post-market (or post-approval) monitoring or surveillance for. Many countries recognize the need for long-term monitoring of the cumulative effects, including benefits, of LMOs. However, there are significant complexities in implementing such programs. The Biosafety Clearing House will facilitate a timely exchange of information about the transboundary movement of LMOs. However, there remain other practical, technical, and economic limitations to monitoring for LMOs to ensure that national and international rules and regulations are respected.

Crosscutting Issues

Crosscutting issues are the ones encountered during each stage of the development and implementation of a national biosafety system, and they are often the most challenging factors to address and resolve. These are the issues that will ultimately dictate the scope of a national policy on biosafety, and the conversion of policy into practice. Crosscutting issues affect the implementation of the system designed to assess biosafety, and perhaps more important, those nontechnical factors that are crucial to the public's acceptance of and confidence in the decisions that are made by government on behalf of the people.

Transparency

The twin issues of public information and participation relate to the degree of transparency in a regulatory system and to the extent to which the public can provide input to the formulation either of a regulatory policy, or of specific regulatory decisions. In this context, transparency refers to the amount and level of information that governments provide on why and how certain products are regulated, on how risk assessments are performed and decisions made, and on what conclusions are reached. Transparency can also relate to the perceived independence and objectivity of the regulatory decision makers. Although closely related, public information and participation have some mutual exclusivity, as it is certainly possible to have an open and transparent process that, however, does not involve public input.

Greater transparency concerning both the risks and benefits of biotechnology products and government decision making is an essential component of building public trust in new technologies. The dissemination of more and better information on agricultural biotechnology is a stabilizing force because, while the public may not generally read scientific studies, risk assessments, or government-decision documents, opinion leaders, members of special interest groups, or others who hope to shape public opinion, do.

Government policy on transparency will determine the extent to which the public and special interest groups will contribute to the development of a national biosafety policy; the opportunities for public participation in the risk-assessment and decision-making process; and the degree to which the public will have ready access to information about the biosafety system, the process of decision making, and the regulatory decisions that are made.

Public Participation

Opportunities for public participation will necessarily reflect the political and cultural environment of a country. Countries with a history of citizen engagement in policy development are likely to include the public in the process of developing a national biosafety system, and the converse is also true. Public participation in the evolution and implementation of a national biosafety system may be the most significant factor in determining the level of public confidence in the risk assessment and management of LMOs.

Mechanisms for public participation include the following:

- advisory committees, particularly those tasked with evaluating the social, ethical, and economic dimensions of biosafety, where one or more members of the public should be included;
- public hearings or individual contributions during the development and amendment of biosafety guidelines and regulations;
- contributions during the risk-assessment process. This will require that the public be informed about products under review and provided with a process through which they can make submissions about the approval of an LMO.

Resources

Human, financial, and infrastructure resources largely determine the scientific and administrative capacity of any country and so obviously influence any biosafety related policy or program (Cohen 2001). Funds must be available to develop and implement a national biosafety system; to support the infrastructure required, e.g., buildings, labs, equipment, and computers; to facilitate communication and public participation; to train scientific and regulatory personnel; and to foster the research required to assure that risk assessments are sound.

Concluding Remarks

Implementing a comprehensive, multifaceted biosafety system responsive to national regulatory needs and to various articles of the Cartagena Biosafety Protocol is a complex, resource-intensive undertaking. The conceptual framework presented here aims to clarify five interrelated elements and decision points for developing a national biosafety system, to examine choices among the various policy options, and to delineate some of the scientific and social dimensions of these options. Neither conceived as a definitive how-to guide for building a national biosafety system, nor designed to be one, the Framework is *a tool for building capacity* in developing countries as they develop or reevaluate their biosafety systems. Further research, case studies, and analysis are being planned to apply this framework to the individual experiences of developing countries.

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